Thoughts on Auditor Training and Audit Sampling

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Auditor Skills…

1. **Communication** – Both oral and written, a person who can be effective with a variety of audiences and at persuasion to secure needed action.

2. **Experience** – Must be broad and encompass the product, manufacturing and support technologies.

3. **Knowledge** – In basic disciplines of the business. Experience in quality technology and statistics are helpful.

4. **Investigation / Judgment Ability** – The ability to evaluate the significance of each item and identify trends and systematic problems – distinguishes an auditor from a reporter.
5. **Peer Acceptance** – Very important. Without it, the auditor credibility is lost and audits will not be effective.

6. **Flexibility** – The ability to adjust rapidly to changing situations. Stable performance under pressure and adverse conditions will enhance the outcome.

7. **Personal Traits** – Dedication, sincerity, enthusiasm, and a sense of humor.
Auditor Competence

Auditor Competence is achieved from a combination of:

- Education
- Work experience
- Auditor training and experience
- Identify potential auditors and evaluate versus personal attributes, skills and knowledge criteria
- Then train and develop each auditor accordingly
Auditor Training – Three Needs

1. Generic Auditing Skills
   - Industry independent
   - Includes company Audit Policy and Procedures
   - Auditing Tools and Techniques

2. Pharmaceutical GMP/Quality Standards

3. Pharmaceutical Technology
Auditor Training

Pre-evaluation

Formal Initial Training

Written/Oral Exam

Experience

Mentoring

Certification

Evaluation

On-going Training, Self Study and Personal Development
Essentials of Effective Audits

1. Planning and Preparation
2. Consistent, Reliable Performance
3. Auditor Listening & Communication Abilities
4. Auditor Constructive Persuasion Abilities
5. Brief, Accurate, Balanced Reports
6. Follow-up System
7. Management Support

The first 6 are key areas for auditor training!
1. Planning and preparation
   - Audit Plan
   - Review Auditee History
   - Checklist development
   - Desk audits (Prereading)
   - Research Travel, Health & Safety, Cultural Issues
2. Consistent, Reliable Performance
   - Well-defined audit objective
   - Qualified people
   - Using agreed-upon standards
   - Able to distinguish the important few from the trivial many

3. Auditor Interviewing, Listening and Communication Abilities
   - Ask, Listen and Confirm understanding
   - Communicate / discuss potential issues or concerns
4. Constructive Persuasion Abilities
   - Seek agreement on the facts
   - Lead others to common conclusions
   - Sets the stage for later root cause by the auditee
   - Leads to more effective corrective and preventive actions

5. Brief, Accurate, Well-Balanced Reports
   - Management summary (strengths and weaknesses)
   - Findings (Conclusions) based on evidence (Observations)
6. Follow Up System
   - Evaluate Auditee Responses
   - Verify Corrective and Preventive actions completed and effective
   - Keep management informed

7. Management Support
Ethics & Professionalism

Conduct

- Communications
- Independence
- Objectivity
- Conflict of Interest
- Sympathy
- Unethical Activities
Communications

Training Point – Be aware of the message you are sending!

*We hear with our eyes as well as our ears*

*We speak with our body as well as our mouth*

- Facial expressions and body movements, however slight, are transmitted without awareness by the auditor.

- This type of communication is powerful that, regardless of the words spoken, a more insightful message is transmitted.
Independence

Training Point - True independence of the audit function is reflected in the quality and objectivity of the audit report.

- Independence helps maintain the objectivity, validity, and integrity of the audit and the audit report

- Auditors should
  - Be free of restrictive influences from their own organization or management
  - Avoid preconceived opinions
Objectivity

- Audit results must be based on verifiable facts and the audit requirements.
- An objective auditor gathers facts as they are presented or uncovered during the audit.
- Personal bias and prejudice must not be an influencing factor.

Training Point – Avoid “It’s not the way my company does it, therefore …”
Conflicts of Interest

- Auditors must be able to recognize and remove themselves from any audit which constitutes real or potential conflict of interest (previous employer, personal relationship, financial interest, etc.)

- The appearance of a “Conflict of Interest” can be as damaging to credibility as the real thing.
Sympathy and Empathy

Empathy (‘I’ve been there – I understand”) facilitates open communication and is appropriate.

Sympathy can compromise your objectivity – feeling too sorry for the auditee may lead you to minimize the significance of audit findings.

Reporting findings and observations in an impersonal and objective manner is the most beneficial action for everyone involved.
Unethical Activities

- Disclosing Confidential Information
- Making derogatory remarks
- Bribery
Auditing References

- Quality Audits for Improved Performance, 2nd ed. – Dennis R. Arter – ASQ Quality Press. (Good, inexpensive intro to auditing)
- ANSI/ISO/ASQ QE 19011S-2004 –Guidelines for quality and/or environmental systems auditing (Good section on auditor competencies, evaluation and training)
Other Audit Training Resources

- Certified Quality Auditor Body of Knowledge
  [www.asq.org](http://www.asq.org)

- Auditor Training DVDs, e.g. “Gorilla in the Midst-Auditing to Add Value”, from QualityCoach.net

GMP Training

- Often similar process as Auditor Training – although most candidate auditors already have core GMP training
- Periodic and Ongoing Training – new strategic business needs, new GMP/Quality Standards, Guidances, and FDA initiatives
- Audit specific topical training
- On-going Self-training and development
GMP Training Resources

- GMP Regulations, US, EU, WHO
- Guidances FDA, EMA, PIC/S, ICH, USP
- FDA Warning Letters, Gold Sheet
- Industry Guidances
  - ISPE Baseline Guides
Other GMP Training Resources

- Many GMPs (EU, etc) provide not only the GMP requirements discuss objectives and approaches
- NEW – ASQ Certified Pharmaceutical GMP Professional Certification (CPGP) *(Has extensive BOK reference list. Some ASQ Sections offer Facilitated CPGP Study Groups/Refresher Courses)*
- Industry Journals and Newsletters *e.g. Pharmaceutical Technology, Biopharm, Journal of GXP Compliance, Journal of Validation Technology, Contract Pharma (many are free)*
- *Active Participation and Networking in Professional Associations (e.g. ASQ, PDA, etc).*
Training in Pharmaceutical Science & Technology for Auditors

Most comments on GMP training and resources apply also here, e.g.

- Most auditors have some prior technical education and work experience
- Many resources and approaches, e.g. In-house seminars, local schools, self-study, dosage form and technology magazines, technical associations
- Network with your own in-house experts (validation, R&D)
A Brief Introduction to Sampling for Auditors
Sampling for Auditors

Why important?

- It’s an area often not stressed in Auditor Training
- As auditors, you are:
  1. Sampling to make a decision about the audited system, …
  2. Often auditing an auditee’s sampling practices
Sampling for Auditors

Some basics - Two Types of Data:

1. **Measurement data** – measured characteristic against a standard, is continuous, subdividable units e.g. 3.1417563… - such as length, time, voltage, etc

2. **Attributes** – countable data with only two states, e.g. go/no go, on/off, good/bad. Always integers – can’t be half good or half bad, e.g. number of errors, parts, cars, etc.

_In auditing, we usually using attribute data and sampling procedures_
Sampling for Auditors

- **Nonconformance** – item that doesn’t meet a requirement or specification

- **Noncompliance** – usually meant as not meeting a procedural or policy requirement

“The auditee was out of compliance with their Quality Policy and was producing nonconforming product”
Defect vs. Defective*

- **Defect** is a failure to meet a requirement which affects fitness for use or safety.
- **Defective Unit** – is any unit of product that contains one or more defects

*Defect and defective may have unintended legal significance. Best to use nonconformance and nonconforming unit in written documents*
Sampling - Two Common Types

**Acceptance Sampling** – QC tool to make Accept/Reject decisions for raw materials, in-process, and final products. Examples include:

- ANSI/ASQ Z1.4 (formerly Mil-Std-105) for Attribute Sampling
- ANSI/ASQ Z1.9 (formerly Mil-Std-414) for variable sampling

1. Generally used for stream of lots from process with known and acceptable process average
2. Generally not suitable for isolated lots with no process history
3. Not usually used for audit sampling
Sampling - Two Common Types

**Discovery Sampling** (aka Exploratory Sampling)
- Type of sampling which provides a specific confidence that errors if present occur no more than some specified rate

1. Commonly used in financial audits. Used in quality auditing when there is very high risk or concern.
2. Can be used on isolated lots, data sets, or without knowledge of the process average for the process producing the items.
Sampling for Auditors

- Auditing is a sampling process.
- We can’t look at everything so we must use a sample to make a decision about the population.
- There is always a risk of making a wrong decision due to sampling error.
Given a lot is 20% defective (i.e., in a true sample of 100 we should find 20 bad), our sampling plan says n=100, and accept on 2 or fewer defectives.

We take a sample of 100 and find no defectives…

- Is that possible?
- What would we conclude about the lot quality?
- Would that be a good decision?
Sampling for Auditors (Cont’d)

Given a lot is 2% defective (i.e., in a true sample of 100 we should find 2 bad defectives) which is considered OK. Our sampling plan says n=100, and accept on 2 or fewer defectives.

We take a sample of 100 and find 50 defectives…

- Is that possible?
- What would we conclude about the lot quality?
- Would that be a good decision?
Sampling for Auditors - RISK

- Alpha Risk ($\alpha$) – the risk of rejecting a good lot (or a true hypothesis)
  - also called Type I Statistical Error or Producers Risk

- Beta Risk ($\beta$) – the risk of accepting a bad lot (or a false hypothesis)
  - also called Type II Statistical Error or Consumers Risk
Sampling Plan - Operating Characteristic Curve

- The risks associated with a specific sampling plan are uniquely described by its Operating Characteristic OC curve.
Sampling for Auditors

TYPICAL O.C. CURVE

LOT PERCENT DEFECTIVE

AQL (.9%)

LQL (2.5%)

RQL OR LTPD (4.5%)
Sampling for Auditors

Training Point - Fixed Percentage Sampling using the same fixed acceptance criteria for all sample sizes (e.g. Accept on 0, Reject on one) is not good practice.

It judges larger lots or populations more harshly than small lots, with increased alpha risk for large lots, increased beta risk on small lots.
Sampling for Auditors

When sampling 10% of the lot size (c fixed)

Note why fixed % sampling plans do not provide the same risks.
Random

- Random Sampling – Ideally every item has an equal chance of being sampled.

- Often Random Number tables are used to select items for examination
Representative (aka Stratified) Sampling

- Representative Sampling – provides assurance that the samples reflect the entire lot by selecting samples from all segments of the lot.

- Think about the process and how defectives might be produced and distributed when deciding how to sample.
Sampling Risk

1. Unless you do perfect 100% inspection, there is always risk.

2. Risk is decreased with larger sample sizes.

3. Larger samples mean more time and greater cost.

4. In auditing, it’s important to recognize that we are making decisions based on small samples.
4. There are no bargains or magic formulas.

5. Your judgment, as you prepare your audit plan, must guide you to look at, what’s important and how many to check.

6. Think about the process and how errors or defectives can occur when deciding how to sample.
An auditor is sampling from a group of documents in which 10% of the documents have random errors / missing data.

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Probability Sample Will NOT Contain an Error</th>
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<tbody>
<tr>
<td>2</td>
<td>81%</td>
</tr>
<tr>
<td>3</td>
<td>73%</td>
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<tr>
<td>5</td>
<td>59%</td>
</tr>
<tr>
<td>10</td>
<td>35%</td>
</tr>
<tr>
<td>50</td>
<td>(\frac{1}{2})%</td>
</tr>
</tbody>
</table>
Then why can we usually use small samples and find so many errors?

- Auditors are doing an additional confirmation – not lot acceptance.
- Often a “small sample” (e.g. 3 records) contain many opportunities for errors.
- Many types of problems are not random but are systematic and repeating.
Types of Audit Sampling

- Judgmental
- Random
- Representative (Stratified Sampling)
- Discovery (a.k.a. Exploratory Sampling)
Discovery Sampling

Provides a specified confidence for a given sample size that the sample will contain at least one error if the error occurs at more than some specified % defective in the population. Methods include:

- Poisson Tables or Graphs
- FDA Inspection Guide - Quality System Inspection Technique, August 1999
- Limiting Quality Tables—ANSI / ASQ Z1.4 (formerly Mil-Std 105F)
- ASQC Q3 – 1998
Poisson Tables in graphical form are probably the easiest discovery sampling methods. For example…

1. If we are able to tolerate a 1% error rate and want to make a 70% confidence statement

2. Read across the 1% defective line to 70% and move down to find the sample size (n = 110)

3. Then, if we find no errors in a sample of 110, we can say with 70% confidence (probability of detection) that if errors occur, then they occur at a rate less than 1%.
Discovery Sampling
Using Poisson Tables in Graphical Form
**Discovery Sampling**

Using Sampling Tables from FDA’s QSIT Inspection Guide

**Table 1**

Binomial Stages Sampling Plans

Binomial Confidence Levels (* ucl = Upper Confidence Level)

<table>
<thead>
<tr>
<th></th>
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<tr>
<td>A</td>
<td>.30 ucl*</td>
<td>11</td>
<td>17</td>
<td>22</td>
</tr>
<tr>
<td>B</td>
<td>.25</td>
<td>13</td>
<td>20</td>
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<td>.10</td>
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<tr>
<td>F</td>
<td>.05</td>
<td>72</td>
<td>115</td>
<td>157</td>
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</table>
### Discovery Sampling

Using Sampling Tables from FDA’s QSIT Inspection Guide

**Table 2**  
**Binomial Stages Sampling Plans**  
**Binomial Confidence Levels** (*ucl = Upper Confidence Level)*

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Sampling - References

- Internal Audit Sampling, Barbara Apostolou and Francine Alleman, The Institute Of Internal Auditors, 1991
- FDA Inspection Guide - Quality System Inspection Technique, August 1999